INTRODUCTION
QUALITY ASSURANCE

Our quality assurance program is designed to identify and minimize the variables in cytogenetic analysis and secondly, to insure delivery of accurate and useful information to the referring physician.

A. Identification and control of variables affecting chromosome analysis

1. Preanalytical events (i.e. sample collection). Sample collection is not performed by our laboratory, however, written procedures are available in the Hospital Laboratory Procedure Manual which is available throughout the hospital or the collection protocols can be obtained from our laboratory. Seminars and lectures are given to housestaff and faculty to heighten awareness and insure correct collection of cytogenetic samples.
2. Analytical and Postanalytical controls are under the subheading "quality control" on the following pages.
3. We participate in the CAP proficiency testing program to assess our diagnostic capabilities and to help identify potential problems.

B. Delivery of accurate and useful information to the referring physician

1. All studies are reported as promptly as possible to insure timely results. This is checked by monthly examinations of our reporting times.
2. Copies of our chromosome reports are sent not only to medical records but also to the referring physician.
3. All chromosome reports use the international approved ISCN nomenclature and include a verbal explanation of our results as well as copies of appropriate references.
4. The medical and laboratory directors are available for consultation.

Our quality assurance program is constantly being evaluated to insure delivery of a high quality and highly accurate clinical service.

THE PRINTED LABORATORY MANUAL IS OFFICIAL REFERENCE OF THIS LAB.

Quality Management Program
Division of Genetics

Responsibility for Implementation

The Director of the Cytogenetics Laboratory is responsible for the desigh, implementation and effective communication during all phases of the Quality Management Program.

Personnel

The director will be a doctoral scientist who is qualified by virtue of documented training, expertise, experience, and certification to meet the standards of the Department of Clinical LAboratory medicine for apointment to the University Faculty.

The technical staff performing Level III testing, as defined by the Federal register 42 CFR (CLIA88) will have a B.S. in the life sciences and board eligible as cytogenetic technologist as registered by NCA.

Continuing Education

The director will meet the continuing education standards of the Department of Clinical Laboratory medicine. This individual will be responsible for maintaining his own records.

All technicians will have 10 hours of continuing education per year. This is accomplished by Division inservice education activities such as teleconferences, seminars, and laboratory meetings. Attendance at professional meetings and workshops are encouraged.

All technical employees must participate in proficiency testing. The individuals are responsible for the accuracy of their continuing education records. Copies of which are to be maintained in their personnel files.

Implementation

The director will verify that monitoring activity covers existing or potential problems, that criteria used for evaluating the monitor are valid, and that a completion date is established. The director will determine if the studies should be ongoing, if the changes were effective, if follow-up action was taken outside the laboratyory, was it effective, and were the results of the QM shared with involved departments. For the review process will appoint a Quality Management Council composed of the director and Division manager/Quality control supervisor. They will meet monthly.

System Operation

The impatct of structure , process and /or outcome on the service to the patient is reviewed. High risk, high volume, or problem prone areas are audited.

Procedures to be monitored

Specimen control
Procedure accuracy
Reporting accuracy

Indicators

Turnaround Times
Culture Failures
Clerical errors

Standards:
Turnaround times vary with sample type and complexity of study. Our turnaround time are in agreement with those followed by the Association of Cytogenetic technologist (Karyogram (15)6,1989). These are <21days Amnio:Peripheral blood routine:<14 days bone marrow; <42 days Solid Tissue for metabolic or cytogenetic studies. Compliance is 100%.

Culture failure is defined as a processed sample that fails to yield suitable metaphase chromosomes. Our standard for compliance is 100% for amniotic fluid: 95% for peripheral bloods: 75% for bone marrows and skin fibroblasts.

Compliance with clerical errors are 100%.

Thresholds of evaluation
Turnaround times
Amniotic fluid: A single slow amnio may signify impeding problems. The total number of samples beyond 21 days will be reported.
Peripheral blood: The threshold is 5% greater than 14 days.
Bone marrow: The treshold is 5% greater than 14 days.
Culture Failures
Amniotic fluid: treshold is 1%
Peripherial Blood: threshold is 5%
Bone marrow: threshold is 50%
Fibroblast: threshold is 50%
Reporting errors
Reporting errors are divide into three categories. Category A error is when the primary care provider has responded to a result by ordering the next test, repeating the test, changing treatment or diagnosis. Threshod is 0%. Category B error is a serious error but unlikely to affect patient care. The primary care provided has not seen or acted upon the report. Threshold is <1%. Category C error is a minor clerical error in reporting and cosmetic corrections to the report. Threshold is twice the average monthly rate during the preceding 12 months.

Corrective Action
Corrective actions are defined by the Quality Assurance Plan depending on the sample type and problem identified.

Evaluation of corrective action
The quality management council will meet monthly. During this meeting the collected data is compared to the defined threshold. The corrective actions needed will be planned and discussed. Recommendations are made for the final monthly reports. Minutes will be taken for each meeting.

Reporting of the detected information
The monthly QM report for Genetics is forwarded to the Department QM committee. Corrective action sheets are included when necessary. After committee review the report is sent to the Hospital Quality Utilization and Management Office.